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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,088	12/05/2001	John W. Sliwa JR.	003-007-C5	2423

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,088

Applicant(s)

SLIWA ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: _____

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Applicant's amendments and comments, received September 30, 2003, have been fully considered by the examiner. In particular, it is noted that claims 92-95 have been newly filed and are the only pending claims in the application. The following is a complete response to the September 30, 2003 communication.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 92-95 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 92 positively recites tissue which is non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 is unclear in the scope of the claim in that it positively recites human tissue. It is suggested the language "adapted to be placed" be inserted after "structure" in line 3 of claim 92, and "are adapted to" be inserted after "elements" in the penultimate line of claim 92 to avoid positive recitation of tissue. This would obviate the 35 USC 101 rejection as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker et al ('084).

It is noted that the Acker et al device has an earliest filing date of March 24, 2000 based on priority to Provisional Application No. 60/192,074. Applicant's earliest prior application which includes support for the subject matter set forth in the instantly pending claims is US Serial No. 09/614,991 filed July 12, 2000. Hence the Acker et al patent is deemed to have an earlier priority date.

Acker et al disclose a device for ablating tissue which comprises a body (10) which forms a loop structure. A plurality of ablating elements (26) are located on the body, each ablating element comprising an emitter of focused ultrasound energy (col. 4, line 36+). Acker et al specifically teach that each element may have a separate focal length, and that the focal length may be varied through tissue (col. 4, lines 60-67). The only features not expressly taught by Acker et al is the specific focal length and focal angle.

It is the examiner's position that the particular focal length and focal angle employed by the device would be inherently related to the tissue being treated and would therefore be an obvious operating parameter associated with the system in a

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given procedure. More particularly, the location and thickness of the tissue being treated would govern the necessary operating parameters and one of ordinary skill in the art would obviously recognize the necessary operating parameters for the procedure.

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199) in view of the teaching of Sanghvi et al ('692).

Jenkins et al discloses an ablation apparatus which includes a loop-shaped body having a plurality of ablation elements located thereon. Jenkins et al teach that the ablation elements are preferably RF electrodes, but also teaches that the ablation elements may be ultrasonic transducers (col. 15, lines 20-26). Jenkins et al fail to disclose the specific type of ultrasonic transducers (i.e. focused).

Sanghvi et al teach of the known use of focused ultrasonic transducers for the ablation of tissue within the body. In particular, the focusing of the transducer allows a particular tissue to be targeted at a particular depth. The examiner again maintains that one of ordinary skill in the art would obviously recognize the necessary focal length and focal angle which would be associated with a given procedure.

To have provided the Jenkins et al device with a plurality of focused ultrasound energy emitters to target specific tissue and tissue depths for treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sanghvi et al.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Knopp et al ('128) and Knopp et al ('811) disclose other devices which include a loop having ablating members located on the loop, whereby the ablating members may be ultrasound transducers.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

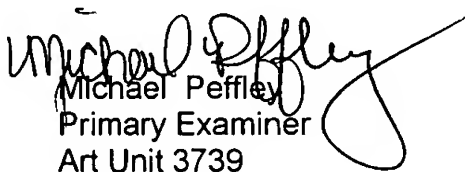
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

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November 12, 2003